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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/471,825	12/23/99	LIN	S 2092/0G278

HM12/0801

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EXAMINER	
WELLS,L	
ART UNIT	PAPER NUMBER
1619	10

DATE MAILED: 08/01/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/471,825	LIN ET AL.	
	Examiner	Art Unit	
	Lauren Q Wells	1619	

-- The MAILING DATE of this communication app ars on the cover she t with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 May 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-55* is/are pending in the application.

4a) Of the above claim(s) *3-5, 10-12, 21, 25-26, 30-32, 29, 48, and 54-55* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,6-9,13-20,22-24,27-29,33-38,40-47 and 49-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4, 6, 9* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Election/Restrictions

Applicant's election with traverse of a Group I and a composition comprising metronidazole, hydroxypropylmethylcellulose, hydrogenated vegetable oil, and the combination of gelatin, xanthan, and amino acids in Paper No. 8 is acknowledged. The traversal is on the ground(s) that it would impose no greater burden upon the Patent Office to search and examine the claims of both groups and that it is unclear as to what the election requires: the single ultimate disclosed species of each specific element or specific species of the composition in total. This is not found persuasive because a) a pharmaceutical composition and a method of making that composition require divergent searches; b) the Examiner in the action mailed on March 29, 2001 specifically laid out the generic species of the composition.

The requirement is still deemed proper and is therefore made FINAL.

It is noted that a telephone call on July 17, 2001 to Andrea Colby clarified a point of confusion in the election/restriction response. Part (e) of the election states "applicants provisionally elect the combination of gelatin, polyacrylic acid polymers crosslinked with polyalkenyl polyethers and amino acids". The polyacrylic acid polymers crosslinked with polyalkenyl polyethers is a water soluble polymer that was not elected. Thus, for part (e) the Applicant's now elect the combination of gelatin, xanthan gum, and amino acids.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 27 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(i) The term "vegetable protein derivatives" in claim 27 (line 2) is vague and indefinite, as it is not clear what other compounds are encompassed by this phrase.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 6-9, 13-20, 22-24, 27-29, 35-37, 41-43, 45, 49-53 are rejected under 35 U.S.C. 102(b) as being anticipated by Huber (4,122,157).

Huber teaches nitrofurantoin sustained release tablets. Disclosed is a tablet comprising two discrete portions, a rapid release portion and a slow release portion, each portion containing a specific quantity of nitrofurantoin. Hydroxypropyl methylcellulose is disclosed as being contained in the slow release portion of the tablet and as comprising 14-42% of the composition. Binders (matrix forming agents) disclosed for use in the fast release layer are starch, gelatin, sucrose, dextrose, molasses, acacia, sodium alginate, carboxymethylcellulose and polyvinylpyrrolidone. Hydrogenated vegetable oil, stearic acid and salts thereof are disclosed as

lubricants for use in the tablet. Disintegrating agents, coloring agents, and flavoring agents are disclosed as additives. A dosage unit form of the composition is disclosed (a tablet). See Col. 1, line 6-Col. 7, line 35.

Claims 1, 2, 6, 7, 25 and 53 are rejected under 35 U.S.C. 102(b) as being anticipated by Iwata et al. (XP-002162841).

Iwata et al. teach a sustained release double layered progesterone suppository for luteal support therapy. Hydroxypropylcellulose and Carpopol were used as bases of the inner layer and WITEPSOL W35 (fatty acid) was used as a base of the outer layer. See entire abstract.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huber in view of Morella et al. (5,378,474) and Gole et al. (5,558,880) in further view of Conte et al. (WO 93/02662) and Saslawski et al. (WO 99/33448).

Huber fails to teach metronidazole, xanthan gum, amino acids, and preferred percentages of the two layers (see above discussion).

Morella et al. teaches sustained release pharmaceutical compositions having a core element and a core coating. Antibiotics disclosed for use as active agents include nitrofurantoin and metronidazole. See Col. 2, line 27Col. 5, line 45; Col. 13, line 65-Col. 15, line 21.

Gole et al. teaches pharmaceutical dosage forms defined by a matrix containing gelatin, pectin and one or more amino acids having form about 2 to 12 carbon atoms. Amino acids disclosed include glycine, alanine, aspartic acid, glutamic acid, hydroxyproline, isoleucine, leucine, and phenylalanine. Other matrix forming agents disclosed include gelatins and xanthan gums. It is further disclosed that polysaccharide complexes may be utilized as matrix forming agents. See Col. 2, line 40-Col. 8, line 55.

Conte et al. teach antiviral pharmaceutical compositions for vaginal administration. A preferred embodiment is pharmaceutical forms devised for a pulsing release of drug (fast release) and a second portion in a prolonged period of time, such as bi-layered vaginal tablets comprising bioadhesive polymers, such as hydroxypropylcellulose and gelatin. The composition is disclosed as containing the active component in an amount from 0.5 to 50%, which meets claims 21, 44 and 46. Another preferred embodiment disclosed is vaginal tablets releasing the drug in a period from some hours to some days, which meets claims 25-26. See pg. 1, line 1-pg. 6, line 26; pg. 9, line 16-pg. 13, line 22.

Saslawski et al. teach a multilayer tablet for the instant (first layer) and then prolonged release (second layer) of active substances. It is disclosed that the active substance may represent up to 99% of the first layer and 98.5% of the second layer. Hydrogenated vegetable oil and hydroxypropylmethylcellulose are disclosed for use in the sustained release layer as binders. See pg. 2, line 19-pg. 12, line 38.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Huber using the teachings of Morella et al. and obtain a composition comprising metronidazole as the active agent because a) Huber and Morella et al. both teach pharmaceutical tablet compositions comprising a sustained release layer; b) Morella et al. teach nitrofuratoin and metronidazole as interchangeable antibiotics for use in pharmaceutical tablet compositions.

Further, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of the combined references by substituting the binder of Huber for the matrix forming agents (binder and matrix forming agent is synonymous) of Gole et al. and obtain a composition comprising gelatin, xanthan gum, and amino acids as matrix forming agents because a) Huber and Gole et al. both teach compositions comprising water soluble polymer and matrix forming agents; b) Huber teaches gelatin and natural and synthetic gums as binders.

Further, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of the combined references using the teachings of Conte et al. or Saslawski et al. and obtain a composition comprising up 99% of an active in the sustained release layer and up to 98.5% of an active in the fast release layer because a) Huber, Conte, and Saslawski all teach compositions in the form of tablets with fast and slow releasing layers; b) Huber, Conte et al., and Saslawski all teach antibacterials as active agents; c) Huber, Conte et al., and Saslawski et al. all teach hydroxypropylcellulose in the sustained release layer.

The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Prior Art

The prior art made of record and not specifically relied upon in any rejections cited above is either 1) considered cumulative to the prior art that was cited in a rejection or is 2) considered pertinent to the applicant's disclosure and shows the state of the art in its field but is not determined by the Examiner to read upon the invention currently being prosecuted in this application.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on M-F (7-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana L Dudash can be reached on (703) 308-2328. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw
July 18, 2001

DAMERON L. JONES
PRIMARY EXAMINER